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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,602	09/05/2000	Anders Carlsson	13454NP	4856

7590

02/12/2002

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 02/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/623,602

Applicant(s)

CARLSSON ET AL.

Examiner

Sharmila S. Gollamudi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 05 September 2000.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Amendment B received on January 3, 2002 is acknowledged.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Rejections of claims 1-7, 9-10, and new claim 13 under 35 U.S.C. 102(b) as being anticipated by Carlsson et al (WO 95/20943) are maintained.

Carlsson et al discloses a topical oil-in water emulsion containing galactolipids in the instantly claimed amounts. The galactolipids are from oats (pg. 7). The composition further contains digalactosyldiaacylglycerol (examples and claims). The reference included glycerol in the composition (examples). Although the reference does not implicitly state that the composition is a lotion, since the reference teaches topical application and since the oil-in-water formulation taught is a liquid, lotion is implicit.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant admits that WO 95/20943 teaches galactolipid material but argues, "nothing in the cited reference is stated about prolonging the effective properties of active substances." Applicant is incorrect in this assumption. WO 95/20943 clearly teaches that "an intrinsic beneficial feature of the galactolipids is the galactose units comprising the polar headgroup in each lipid molecule, which may sterically stabilize the

Art Unit: 1616

emulsion droplets, and thus provide for a prolonged life-span when injected into the blood stream" on page 5, lines 1-5.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Rejection of claims 1-11 and new claim 13 under 35 U.S.C. 103(a) as being unpatentable over Carlsson et al, are maintained.

As set forth above Carlsson et al teach the instantly claimed composition for topical application and the preparations contain dermatological drugs (page 5, 3rd paragraph).

The reference does not explicitly teach the forms of topical application such as lotions, creams, etc. Further, the reference does not teach the specific dermatological agents.

It is deemed obvious to one of ordinary skill in the art to choose an appropriate form of the composition with the expectation of obtaining the best possible results. Also, it is obvious to one of ordinary skill in the art at the time the invention was made to incorporate the desired active agents such as steroids, anti-dermatitis agents and anti-psoriatic agents, if inflammation, dermatitis and psoriasis are the conditions to be treated.

Art Unit: 1616

The rejections are maintained since the applicant does not provide specific arguments regarding the 103 rejections. The only argument applicant provides is that Carlsson et al does not teach using galactolipids to prolong the effectiveness properties of active substances. This argument has been addressed in the above argument.

Rejection of claims 10-11 under 35 U.S.C. 103(a) as being unpatentable over Carlsson et al cited above in combination with Yamada et al (5,885,978), are maintained.

Carlsson et al teach a topical oil-in-water emulsion containing galactolipids as set forth above. Further, Carlsson et al teach the incorporation of dermatological agents.

The reference does not teach the incorporation of instantly claimed steroid.

Yamada et al teach that steroidal drugs are useful in the treatment of atopic dermatitis. The compositions may be in the form of emulsions (note the abstract, col. 3, lines 5-15 and Tables).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Carlsson et al and Yamada et al since Carlsson et al teach the use of dermatological agents in the emulsion and Yamada et al teach that steroids in emulsion form are routinely used for the treatment of these inflammation. Alternately, the use of the emulsions of Carlsson et al in the teachings of Yamada et al would have been obvious to one of ordinary skill in the art since Carlsson et al teach that these emulsions are surprisingly stable (note pages 6 and 7).

The rejections are maintained since the applicant does not provide specific arguments regarding the 103 rejections. The only argument applicant provides is that

Art Unit: 1616

Carlsson et al does not teach using galactolipids to prolong the effectiveness properties of active substances. This argument has been addressed in the above argument.

Rejection of claim 12 under 35 U.S.C. 103(a) as being unpatentable over Carlsson et al cited above, in view of Horrobin (4444755), is maintained.

Carlsson et al teach a topical oil-in-water emulsion containing galactolipids as set forth above. Further, Carlsson et al teach the incorporation of dermatological agents.

The reference does not teach the incorporation of instantly claimed anti-psoriasis agent.

Horrobin teaches the use of various essential fatty acids for the treatment of skin conditions such as psoriasis (see abstract, col. 1, line 18 through col. 3, line 39; col. 4, lines 25-46).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Carlsson et al and Horrobin. One would be motivated to do so since the use of the claimed essential fatty acid as the are known for their effectiveness in the treatment of skin conditions such as psoriasis as evident from Horrobin. Alternately, as pointed out above, the use of the emulsions of Carlsson et al in the teachings of Horrobin would have been obvious to one of ordinary skill in the art since Carlsson et al teach that these emulsions are surprisingly stable (note pages 6 and 7).

The rejections are maintained since the applicant does not provide specific arguments regarding the 103 rejections. The only argument applicant provides is that

Art Unit: 1616

Carlsson et al does not teach using galactolipids to prolong the effectiveness properties of active substances. This argument has been addressed in the above argument.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Correspondence

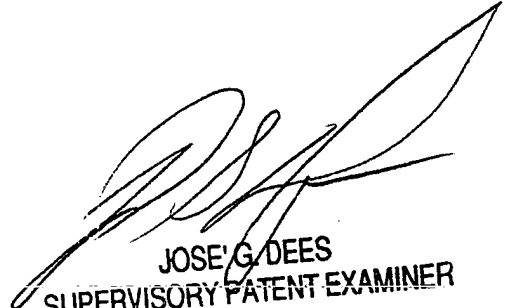
Any inquiry concerning this communication from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can be normally reached M-F from 7:30 am to 4:15pm.

If attempts to reach the examiner by the telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached at (703) 308-4628. The fax number for this organization where this application or proceeding is assigned is (703) 308-4556.

Art Unit: 1616

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, whose telephone number is (703) 308-1235.

~~SSG~~
SSG
1/28/02


JOSE G. DEES
SUPERVISORY PATENT EXAMINER
1616